K120059

MAY 17 2012

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ChessonLabs

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

510(k) owner's name: Chesson Laboratory Associates, Inc.

Address: 603 Ellis Road, Durham, North Carolina 27703

Phone and fax numbers: (919) 957-1797; (919) 957-7072

Name of contact person: Lance L. Swick, Ph.D.

Date of Summary: May 15, 2011

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Name of device:

Trade or proprietary name: to be determined

Common or usual name: Liquid bandage

Classification name: CFR 880.5090 Class I

Legally marketed device to which equivalence is claimed: Ecocel® [K083087]

Product description:

This product for nail dystrophy is a biocompatible, polymeric lacquer that is applied directly to the nail. The product is dispersed in a solution that dries rapidly, adhering to the contours of the nail to form a transparent, colorless, flexible, waterproof barrier.

Intended use of device:

[The device] is indicated for managing signs and symptoms of nail dystrophy, i.e., nail splitting and nail fragility, for intact or damaged nails. [The device] coats and adheres to the nail surface preventing direct abrasion and friction on the nail surface while also providing protection against the effects of moisture.

Technological characteristics:

Biocompatibility of the product was evaluated per ISO-10993 for cytotoxicity, sensitization, and irritation, acute systemic toxicity, genotoxicity, mutagenicity, pyrogenicity, and implantation. Twelve different types of tests were run and the product was shown to be biocompatible.

Bench testing of the bulk formulation and packaged product included molecular weight, water content, setting/drying time, viscosity, percent solids, color and particulates, heat of polymerization, as well as moisture vapor transmission rate, tensile strength, aqueous and acetonitrile extractions of the dried film to confirm absence of degradation products, and distribution/ship tests of the packaged product. Performance characteristics of the product are substantially equivalent to those of the predicate device.

Chesson Labs has submitted summaries of preclinical lab test results, including determinations for anti-abrasion and evaluations for film-forming capacity, friction, and protective properties against chemical agents. Safety of the product was further defined in a clinical study where the product was applied to the nail for approximately six months.

Chesson Labs believes the preclinical studies, clinical safety studies and information comparing the products technological features provided in the application demonstrate the product's substantial equivalence.

Summary of New Device to Predicate Devices

Parameter	**Device**	**Predicate Device**
Device Name	TBD	Ecocel
Company Name	Chesson Laboratory Associates, Inc.	Polichem S.A.
510[k] #	TBD	K083087
Class	I	I
21 CFR Number	880.5090	880.5090
Code	KMF	KMF
Code Description	Liquid bandage	Liquid bandage

Parameter	Device	Predicate Device
Product Type	Device	Device
Format	Applicator	Applicator
Ancillary Components	None	None
Intended Use	Indicated for managing signs and symptoms of nail dystrophy, i.e., nail splitting and nail fragility, for intact or damaged nails. Product coats and adheres to the nail surface preventing direct abrasion and friction on the nail surface while also providing protection against the effects of moisture.	Indicated to protect intact or damaged nails from the effects of moisture, friction (rubbing) or shear (tearing), relieving symptoms and signs of nail dystrophy (i.e. nail splitting and fragility).
End Use	Prescription, OTC	Prescription, OTC
Frequency of Use	Once daily	Once daily
Components	Poly(urea-urethane) polymer in organic solvents	Hydroxypropyl-chitosan, equisetum arvense and methyl sulfonyl methane in organic solvents
Testing	Biocompatibility; preclinical studies; laboratory studies; clinical studies	Biocompatibility; preclinical studies; laboratory studies; clinical studies; post-market experience in Europe

Comparison Statement:

Chesson Labs' product is similar to the predicate device in that it provides the same functions as Ecocel®, has similar claims, and has similar indications for use. Both of these products are liquid solutions applied directly to the nail, which upon contact with the nail dry to form a film. They have many of the same functional characteristics, such as ability to cover the keratin grooves of the nail as well as protect the nail from exposure to environmental factors.

Results of biocompatibility and design verification testing have demonstrated that the Chesson Labs' product has the same descriptive, technical, and safety characteristics and therefore raises no new no new issues of safety or effectiveness. The Chesson Labs' product to manage symptoms and signs of nail dystrophy has similar technological characteristics as the previously cleared product [Ecocel; K083087]. Chesson Labs has considered the impact upon safety resulting from the extended duration of product use and has supported the safety for the new intended use of this product in clinical studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 17 2012

Chesson Laboratory Associates, Inc.
% Lance Swick, Ph.D.
603 Ellis Road
Durham, North Carolina 27703

Re: K120059
Trade/Device Name: Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: Class I
Product Code: KMF
Dated: April 30, 2012
Received: May 03, 2012

Dear Dr. Swick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120059

Indications for Use

510(k) Number (if known): _____

Device Name: TBD

Indications for Use:

[The device] is indicated for managing signs and symptoms of nail dystrophy, i.e., nail splitting and nail fragility, for intact or damaged nails. [The device] coats and adheres to the nail surface preventing direct abrasion and friction on the nail surface while also providing protection against the effects of moisture.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices